For the Northern District of Californi

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IN THE U	INITED STATES DISTRICT COURT						
FOR THE NO	FOR THE NORTHERN DISTRICT OF CALIFORNIA						
FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.,	No. C 03-1431 SBA						
Plaintiffs,	ORDER						

[Docket No. 597]

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

This matter comes before the Court on Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion to Strike the Declaration of Richard Alan Griewski. Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby GRANTS IN PART AND DENIES IN PART Baxter's Motion to Strike the Declaration of Richard Alan Griewski [Docket No. 597].

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this patent suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"). Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("'434 Patent"); (2) U.S. Patent No. 5,326,476 ("'476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("'131 Patent"); (4) U.S. Patent No. 5,486,286 ("'286 Patent"); and (5) U.S. Patent No. 5,744,027 ("'027 Patent") (collectively

"patents-in-suit").

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On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its answer and counterclaims to assert infringement of the '286 Patent.

On October 11, 2005, Richard Alan Griewski was deposed by Fresenius and Baxter as a fact witness.

On February 21, 2006, Fresenius filed a Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patents Nos. 6,284,131 and 5,247,434 asserting obviousness, anticipation, best mode, and enablement affirmative defenses.

On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity on Fresenius' anticipation, best mode, and enablement defenses.

On March 21, 2006, Fresenius filed an Opposition to Baxter's Motion for Partial Summary Judgment, as well as the Declaration of Richard Alan Griewski in Opposition to Defendants' Motion for Partial Summary Judgment of Validity (the "Griewski Declaration"). Mr. Griewski is currently a principal engineer in research and development at Terumo Medical Corporation ("Terumo"). Griewski Decl. at ¶ 1. He holds a bachelor of science degree from University of Michigan, which he received in 1978, and a degree in electrical engineering from University of Michigan, which he received in 1985. Id. at 2. Following his graduation from University of Michigan in 1985, Mr. Griewski was employed by a company called Sarns/3M. *Id.* at ¶ 3. At Sarns/3M, Mr. Griewski worked on the development of a heart lung machine called the Sarns 9000. *Id.* at ¶ 4. In fact, Mr. Griewski was the lead engineer on the development of the touch screen user interface on the Sarns 9000. Id. Mr. Griewski was also responsible for several other aspects of the user interface on the Sarns 9000, including the layout of many of the buttons (called "membrane switches"), the control knobs, and the temperature monitoring system. Id.

Following the development of the Sarns 9000, Mr. Griewski also worked on the development of other heart lung machines, namely the Sarns 8000 and the System 1. *Id.* at ¶ 5.

On March 28, 2006, Baxter filed the instant Motion to Strike the Declaration of Richard Alan Griewski. In its Motion to Strike, Baxter argues that the Court should strike the Griewski Declaration

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pursuant to Federal Rules of Civil Procedure 26(a)(2)(A) and 37(c)(1) on the grounds that Fresenius failed to disclose Mr. Griewski as an expert, or to submit a written expert report, by the Court-ordered deadlines.

LEGAL STANDARD

Federal Rules of Civil Procedure 26 and 37 A.

Pursuant to Federal Rule of Civil Procedure 26(a)(2), a party is required to "disclose to other parties the identity of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence." Fed. R. Civ. P. 26(a)(2)(A). Further, under Rule 26(a)(2)(B):

> [The] disclosure shall, with respect to a witness who is retained or specially employed to provide expert testimony in the case or whose duties as an employee of the party regularly involve giving expert testimony, be accompanied by a written report prepared and signed by the witness. The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.

Fed. R. Civ. P. 26(a)(2)(B).

Under Federal Rule of Civil Procedure 37(c)(1), "[a] party that without substantial justification fails to disclose information required by Rule 26(a) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed." Fed. R. Civ. P. 37(c)(1).

Federal Rules of Evidence 701 and 702 В.

If a witness renders an opinion as a lay witness, that opinion must comply with Federal Rule of Evidence 701, which states:

> If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical or other specialized knowledge within the scope of Rule 702.

Fed. R. Evid. 701.

Pursuant to Rule 702:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

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Thus, under Rule 701, any part of a witness' testimony that is based upon scientific, technical, or other specialized knowledge within the scope of Rule 702 is governed by the standards of Rule 702 and the corresponding disclosure requirements of the Federal Rules of Civil Procedure. This "eliminate[s] the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing." Fed. R. Evid. 701 Advisory Committee Notes to 2000 Amendment. Since it is possible for the same witness to provide both lay and expert testimony in a single case, however, the Court is required to distinguish between expert and lay testimony, not just expert and lay witnesses. Id.

ANALYSIS

With respect to the instant Motion to Strike, neither party disputes that Mr. Greiwski was not disclosed as an expert witness and that Mr. Griewski has not submitted an expert report. Further, neither party disputes that, since Mr. Griewski was not disclosed as an expert, any testimony falling within the ambit of Rule 702 must be excluded. The dispute therefore centers upon whether Mr. Greiwski is providing solely lay testimony, solely expert testimony, or a combination of both lay and expert testimony in his Declaration. Baxter argues that the entire Griewski Declaration must be stricken because it consists of expert testimony pertaining to "technical or other specialized knowledge," such as statements comparing the Sarns 9000 to the '131 Patent, which is governed by Rule 702. Fresenius, on the other hand, argues that the Griewski Declaration is admissible because Mr. Griewski is merely providing lay testimony pertaining to the Sarns 9000, which is within the scope of his knowledge as a layperson since he helped design the Sarns 9000 while employed by Sarns/3M.

Having reviewed the Griewski Declaration in its entirety, the Court finds that some of the statements contained in the Declaration exceed the scope of lay testimony and should be stricken. While Fresenius is correct that courts regularly allow lay witnesses, such as Mr. Griewski, to testify with

regard to their personal knowledge of a particular invention or piece of prior art, see, e.g., Corning, Inc.
v. SRU Biosystems, 2005 WL 2465900, *7-8 (D. Del. 2005), the mandate of Rule 701 is clear. Lay
opinion testimony is "not to provide specialized explanations or interpretations that an untrained layman
could not make if perceiving the same acts or events." U.S. v. Conn, 297 F.3d 548, 554 (7th Cir. 2002).
As stated by the district court in Gart v. Logitech, Inc., 254 F. Supp. 2d 1119, 1123 (C.D. Cal. 2003),
when "declarants compare [prior art] to the [] Patent, they provide testimony that require[s]
specialized knowledge." <i>Id.</i> "This they are not permitted to do as laypersons." <i>Id.</i>

As such, Mr. Griewski's testimony concerning the Sarns 9000 – to the extent that it is premised on his personal knowledge regarding the machine and the way that it operates – is admissible. However, Mr. Griewski may not offer opinion testimony comparing the Sarns 9000 to the '131 Patent. Further, to the extent that Mr. Griewski provides opinions pertaining to whether certain components of hemodialysis and/or heart lung machines were well known in the industry, and does not base his opinions on personal observations relating to his employment at Sarns/3M, this testimony is also inadmissible.

Accordingly, the Court hereby STRIKES the following statements from the Griewski Declaration:

¶7 - "I have reviewed one of the patents in suit, U.S. Patent No. 6,284, 131. I have also reviewed the asserted claims of the '131 patent. In particular, I have reviewed the language in part (b) of claim 1 of the '131 patent:

(b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis apparatus, the touch screen being operable to display an indicum permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa."

¶9 - "Therefore, the abscissa is time-based."

¹See also B & G Plastics, Inc. v. Eastern Creative Indus., Inc., 2004 WL 307276, *8 (S.D.N.Y. 2004) (stating that, in determining the admissibility of a lay witness' opinion testimony, "a witness' experience and specialized knowledge obtained in his or her vocation should certainly be taken into consideration"); see Braun Corp. v. Maxon Lift Corp., 282 F. Supp. 2d 931, 934 (N.D. Ill. 2003) ("[I]t has been held that an inventor is a competent witness to explain the invention and what was intended to be conveyed by the specifications and covered by the claims.").

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¶ 10 -	"It corresponds	directly to	the blood	pump :	flow rate	parameter	disclosed in	the '	131
	patent at column	n 8. lines 2	27-37."						

- "I note that claim 1 of the '131 patent requires the 'display' of the time-variable profile. The '131 patent makes clear that the display of the time variable profile is done on a standard Cathode Ray Tube monitor or 'CRT' monitor. This is clear both from Figure 7 of the '131 patent which shows element 503 is the CRT display and from the description of the invention which makes clear that the display of data occurs on the CRT ('131 patent at 12:48-49). A CRT monitor is a type of monitor that was well known long before the 1990 priority date of the '131 patent. Prior to 1990, CRT monitors had been used for years as displays for computers in millions of homes and offices."
- "It was well known by 1990 that graphical information could be displayed on those monitors. This would certainly have included graphical information of the type shown as an example in Figure 10 of the '131 patent. It would also have included graphical information shown on the graphical display of the Sarns pulsatile screen."
- "The touch screen is a separate component from the display. Again, this is clear from Figure 7. The touch screen is element 501. A touch screen is, essentially, nothing more than a clear piece of plastic or other material that generates a signal when a zone on the touch screen is touched. The signal can be sent to a computer and tells the computer which zone of the touch screen was touched. The way these machines work is that the touch screen is mounted over the front of the display (whether graphical images such as profiles or buttons or text) are 'mapped' to the zone on the touch screen immediately in front of the image. Users of the machine view the CRT display through the clear touch screen. While users perceive that they are touching a graphical image or button on the CRT display, in reality they are touching the touch screen which is overlaying the CRT display. By 1990, it was well known that touch screens could be used with CRT displays on various medical devices. It was also well known by 1990 that graphical images could be displayed on CRT screens."2
- "I also disagree with Baxter's second and more general argument that the idea of using a touch screen to monitor and control hemodialysis machine parameters was a unique or innovative idea as of April 1990. Heart lung machines and hemodialysis machines are very similar machines in many respects. Both machines use roller pumps to circulate a patient's blood outside the body, treat the blood, and then return it the body. Both machines have to monitor parameters associated with this process such as blood flow rate, blood pressure, and blood temperature. Both machines also require various safety systems and alarms to ensure that if something unexpected or undesired occurs during the extracorporeal circulation and treatment of the blood corrective actions can be taken quickly. Many of the same or similar machine parameters that are monitored or controlled during cardiac bypass are also monitored or controlled during hemodialysis."

Again, the above-referenced statements are clearly inadmissible expert testimony because they are based on "scientific, technical or other specialized knowledge within the scope of Rule 702" and exceed the scope of permissible lay testimony. As such, they have not been considered by the Court.

²This testimony is inadmissible because it appears that Mr. Griewski is testifying with regard to the touch screens described in the '131 Patent, rather than his personal knowledge of the way that the touch screen in the Sarns 9000 operates.

Case 4:03-cv-01431-PJH Document 657 Filed 05/15/06 Page 7 of 7

The remainder of the Griewski Declaration is admissible and has been considered.
CONCLUSION
IT IS HEREBY ORDERED THAT Baxter's Motion to Strike the Declaration of Richard Alan
Griewski [Docket No. 597] is GRANTED IN PART AND DENIED IN PART.
IT IS SO ORDERED.
Saundre B Grosting

SAUNDRA BROWN ARMSTRONG United States District Judge Dated: 5/15/06